

**Amendment #1**  
**to RFP-NIH-NIAID-DMID-03-04**  
**" Food and Waterborne Diseases Integrated Research Network"**

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<b>Amendment to Solicitation No.:</b>	NIH-NIAID-DMID-03-04
<b>Amendment No.:</b>	1
<b>Issue Date:</b>	September 6, 2002
<b>Effective Date:</b>	September 6, 2002
<b>Proposal Due Date:</b>	November 18, 2002, at 4:00 P.M. local time
<b>Issued By:</b>	Lawrence M. Butler Senior Contracting Officer NIH/NIAID Contract Management Branch 6700 B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
<b>Point of Contact:</b>	Kristen Mistichelli Contract Specialist KM359d@nih.gov
<b>Name and Address of Offeror:</b>	To All Offerors

The above numbered solicitation is amended as set forth below. The hour and date specified for receipt of proposals **HAS NOT** been extended. Offerors must acknowledge receipt of this amendment. Failure to receive your acknowledgement of this amendment may result in the rejection of your offer. This amendment shall be acknowledged in the following manner:

- By acknowledging receipt of this amendment on each copy of the offer submitted.

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**DESCRIPTION OF AMENDMENT (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)**

RFP TITLE: *"Food and Waterborne Diseases Integrated Research Network "*

**PURPOSE:**

- 1.) Other AGENTS
- 2.) Replace Comparative Importance of Proposals, Section L – General Information, paragraph g.
- 3.) Add additional guidance for Proposal Evaluation, General, Section M.
- 4.) To add guidance regarding the USA Patriot Act
- 5.) To answer questions received in response to this solicitation.

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**AMENDMENT:**

- 1.) OTHER AGENTS  
This interdisciplinary consortia will address food and waterborne pathogens (bacteria, viruses, and protozoa included in the NIAID Category A, B, C priority organisms list). At the discretion of the Project Officer, agents not listed in the NIAID Category A, B, C list may be addressed (for example other enteric and hepatic pathogens i.e., *Helicobacter pylori*, hepatitis viruses).
- 2.) SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS, Paragraph 1. GENERAL INFORMATION, Item ( g.) COMPARATIVE IMPORTANCE OF PROPOSALS. Delete and replace with:

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

3.) SECTION M – EVALUATION FACTORS FOR AWARD, Paragraph 1. GENERAL, add the following:

The need to create a balanced Food and Waterborne Diseases Integrated Research Network that can meet DMID program priorities is critical and will be considered in making awards.

4.) The following provisions apply to this solicitation and are hereby incorporated:

The Offeror/Contractor acknowledges that U. S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. Specifically, P.L. 107-56, the Patriot Act of 2001 (<http://www.ins.usdoj.gov/graphics/lawsregs/patriot.pdf>) states that a wide range of people defined as "restricted" cannot work with pathogens or toxins that are potential biodefense agents. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its territories, then the offeror must indicate in the proposal that these individuals have the required visas (i.e. are permanent residents and have "green card"). The contractor or Institution that receives an award under this RFP is responsible for applying this law.

5.) The following answers to questions received in response to this solicitation are provided for your information:

Question 1: Do you think it is better to have two proposals from this University, for two units, or would it be better to combine the two?

Answer 1: The RFP requires that they submit separate proposals. Each proposal should stand alone, and will likely be sent to separate reviewing bodies. It is important to include all data required to evaluate the proposal in each Unit's proposal. Nothing should be combined.

Question 2: Is it expected that co-investigators for the unit would have expertise with every category A, B and C organism listed or is the focus mainly on the food and water-borne pathogens listed in category B? Is this enough or is it expected that outside collaborators would be needed for the other food/water organisms to be a part of this ZRU?

Answer 2: The emphasis is on food and waterborne pathogens listed in category B, but does not exclude food and waterborne pathogens in Categories A-C (e.g., *Francisella tularensis* listed in Category A, may be transmitted in food and/or in water). The expectation is that each unit will have research expertise in a representative number of the food and waterborne pathogens. Each ZRU is encouraged to identify outside collaborators to enhance the breadth of the expertise of the unit, to the extent that it is reasonable. It is not necessary to assemble a team to cover all of the Category A-C pathogens.

Question 3: The required contents of the research component of the proposal were not clear to me. Is it acceptable for each of the co-investigators to describe their research program as related to Items 5 and 6 (pages 9&10) under the Statement of work for Part C ZRU besides addressing the other items(1-6)? Can these research sections be described separately for each pathogen?

Answer 3: Yes, it is acceptable for each of the co-investigators to describe the research program as related to items 5 and 6 (pages 9 & 10) under the Statement of Work for Part C ZRU and address items 1-6. The research sections may be described separately for each pathogen.

Question 4: Is this RFP soliciting contractors (service laboratory) and only involves studies initiated by the Project Officer or are you requesting PI-initiated research in the Food and Waterborne Diseases Research Area?

Answer 4: The FWD IRN Executive Committee will participate in the review of proposed research projects and make recommendations to the Project Officer as to those that should be conducted by the FWD IRN. Ad Hoc consultants will provide advice to the NIAID regarding research priorities and projects in food and waterborne diseases. The PI is expected to propose research projects.

Question 5: Must all the PI initiated research data (logbooks, labbooks, electronic data, experimental materials, computer

files, etc) be turned over to the Project Officer at the end of the contract?

Answer 5: The contractor will need to provide copies of all information and research data which is relevant to the successful transition of this project to a subsequent contractor, particularly if the data is necessary to continue research linked to samples, future studies etc. Experimental materials needed for continuation of the contract activities will need to be transferred to the next successful contractor.

Question 6: Are research publications permitted from the work supported by these contracts?

Answer 6: Research publications are permitted and encouraged.

Question 7: We are a part of the (Federal Service). We are eligible to apply for NIH grants, but I want to make sure that we are also eligible to be considered for this contract. Are we?

Answer 7: Many federal service organizations are eligible for NIAID contracts.

Item 6.d., indicates that the offeror must establish and enhance existing collaborations with other government agencies, e.g., USDA, FDA, CDC, local and state public health and or animal health departments and laboratories. We suggest that you partner with a potential offeror(s) to help them meet this requirement.

Question 8: Are you looking for a single contractor to work with all the food and waterborne pathogens in the priority lists, or can a single proposal focus on a subset of the organisms? In our case, we have experience with most of the bacteria that could be food or waterborne, but not the viruses and protozoa. Should we look for consortium partners to completely cover the list before preparing a proposal?

Answer 8: The expectation is that each unit will have research expertise in a representative number of the food and waterborne pathogens. Each unit should consider identifying outside collaborators to enhance the breadth of the expertise of the unit, to the extent that it is reasonable.

Question 9: The RFP states that at the end of the contract, specimens are supposed to be returned to NIH. Will contractors be allowed to keep aliquots of these specimens at their institution?

Answer 9: Yes, if sufficient volumes are available.

Question 10: Will NIH be providing level-of-effort guidelines for the individual research units?

Answer 10: The following ANNUAL level of effort estimates are provided for informational purposes only. It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately as provided below. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

Title	Rate	Hours
<b>A: Clinical Units--EACH SITE</b>		
Direct Labor		
PI	40%	832
Professional -Investigators	100%	2080
Professional--RN	200%	4160
Technical Staff	200%	4160
Support Staff	100%	2080
Total D.L.	640%	13312

**B. Microbiology Units--EACH SITE**

Direct Labor		
PI	20%	416
Professional Staff	100%	2180
Technical Staff	300%	6240
Support Staff	50%	1040
Total D.L.	470%	9876

**C. Immunology Units--EACH SITE**

Direct Labor		
PI	20%	416
Professional Staff	100%	2080
Technical Staff	200%	4160
Support Staff	50%	1040
Total D.L.	370%	7696

**D. Zoonosis Units--EACH SITE**

Direct Labor		
PI	25%	520
Professional	200%	4160
Animal Care Staff	200%	4160
Technical Staff	200%	4160
Support Staff	50%	1040
Total D.L.	675%	14040

Question 11: The RFP synopsis indicated that DMID is re-competing and expanding the program previously held by the university of Maryland. Can you provide any information on the details of this previous program in terms of period of performance, the funding level and the University's Principal Investigator?

Answer 11: Contract N01-AI-65299 entitled Enteric Pathogens Mucosal Research Unit was awarded for the not to exceed amount of \$13,631,379. The performance period is from 1/22/96 through 1/21/2003. The Principal Investigator is Carole Tacket.

Question 12: Can you provide information on NIH's estimate of the total value of the overall program? If possible can this be presented for the first year of activates and the total 7 year value estimate.

Answer 12: The estimated annual labor hours have been provided, above.

Question 13: Can you provide information on NIH's estimate of value the individual contract awards?

Answer 13: No additional information can be provided regarding the Government's independent cost estimate.

Question 14: Does NIH anticipate that the contract value for the 4 research unit areas will be approximately the same?

Answer 14: No. Award amounts will be driven by the proposals submitted and the combination of awards made.

Question 15: Does NIH anticipate that contract value for some research unit areas will be at a higher funding level than others? If so can you provide some information on the government estimates.

Answer 15: Please review earlier responses. No additional information can be given at this time.

Question 16: Is there any information available on the NIH website or other media that will provide a briefing of the anticipated funding.

Answer 16: Please review earlier responses. No additional information can be given at this time.

Question 17: Have these programs achieved funding authorization in the FY03 budgets?

Answer 17: These activities are internally planned for FY03. While NIAID expects to award contracts in support of the program, the Government is not obligated to do so. The final appropriations for NIH has not been approved.

Question 18: Is NIAID expecting researchers to come in with proposed research topics? Is it better to have a few topics, or submit many which are under various stages of development? Is the submission of our research ideas similar to what is expected under an R-01?

Answer 18: The NIAID is expecting researchers to come in with a few research plans which will address the items in the statement of work. The submission of research ideas should emphasize the applied scientific approaches.

Question 19: Is it more advantageous for a university to submit more than one proposal, for more than one Unit? Will we stand a better chance of receiving an award under this scenario?

Answer 19: Awards will be based on scientific merit. It is not necessarily advantageous for a university to submit more than one proposal, for more than one unit. The emphasis of the FWD IRN network is on integrated research activities. It is important to show evidence of (past or present) collaborative research outside the unit to provide support for the ability to network with other units.

Question 20: The second question is that for the Zoonosis center it says that the PI should be a veterinarian. How firm is that?

Answer 20: It is required that the PI be a veterinarian for the Zoonoses Research Unit. The Zoonoses Research Unit emphasizes animal-human diseases, ecology, epidemiology and collaborative research with federal agencies with agricultural responsibilities. For this reason, the training and professional relationships of the veterinarian are important. The research projects should include all relevant disciplines including PhDs, Masters of Preventive Medicine, Masters/PhD Public Health etc.

Question 21: There are no guidelines with regard to anticipated scientific, technical and administrative input for the purpose of budget calculations of the number and percentage effort.

Answer 21: Please refer to the answer to question 10.

Question 22: No guidelines with regard to the proportion of time/effort which will be devoted to basic/developmental research, and for testing/investigative/diagnostic activity.

Answer 22: Please refer to the answer to question 10 and 18. The emphasis should be on applied research, testing, investigative, and diagnostic activities. The effort will depend on the state of the science and the research question, which will vary with the state of the science for the agent under study.

Question 23: Is it expected that the team will provide an outline for basic/developmental research for the entire 7 years? Is the intention to then use the team in time of emergency to carry out testing/investigation/diagnostic task?

Answer 23: It is expected that the team will identify activities to be complete in year one and propose some activities that may be carried out over the entire 7 years. The Project Officer may make specific requests of the team at any time during the contract period. It is the intention to use the team in time of emergency to carry out testing/investigation/diagnostic task (s).

Question 24: The lack of proposed scientific and technical input also limits planning of the scope of research and developmental work to be performed. It also limits the ability to accurately calculate the budget for supplies, space, animals, subcontracts, etc.

Answer 24: Please see the responses to the questions above. If you need further clarification please let us know.

Question 25: How much authority will the Steering Committee have over what is performed, in the absence of a national emergency, for approved Units?

Answer 25: The Steering Committee will not have authority. However, the Steering Committee will provide a consensus opinion as to the research projects that should be performed and or should be continued or discontinued, by the FWD IRN. The opinion will be provided to the Project Officer. The Project Officer may decide or request outside expert advice, if deemed appropriate.

Question 26: With regard to the food and waterborne disease contract, contract language states "agents in the NIAID category A, B, C priority organisms list which are transmissible through and/or water". Do this only refer to the agents in the B list under "Food and Waterborne pathogens? Can we add to that list. The agents in question are: *Leptospira* spp and *Mycobacterium avium*?

Answer 26: Please see the amendment "Other Agents". The agents e.g. *Leptospira* spp and *Mycobacterium avium* may be studied but this will be done at the request of the Project Officer. The proposal should respond to the request for proposals for agents in the NIAID category A, B, C.

Question 27: In your Notes to Offerors on the CRU (page 13 of PDF), note #3 states that we should assume that studies will be inpatient. Under this assumption, all note #4 studies would all be inpatient, and note #5 studies would be a mix of inpatient and outpatient. On the other hand, note #3 lists studies both outpatient and inpatient studies. Please advise us on how to proceed, as the inpatient/outpatient dichotomy has important implications for cost estimates.

Answer 27: Note (3) should state that the offeror should assume that some of the studies will require that volunteers be studied as inpatients. The examples then follow appropriately as #3 lists both outpatient and inpatient studies.

Question 28: How about industry-contractor collaborations?

Answer 28: Yes. All collaborations are encouraged.

-END-

Except as provided herein, all terms and conditions of RFP NIH-NIAID-DMID-03-04 remain unchanged.